

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO PAR
INNOVATION COMPANY, LLC

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS COMPANY
GMBH, AMNEAL PHARMACEUTICALS OF
NEW YORK, LLC, AMNEAL BIOSCIENCES
LLC, AMNEAL PHARMACEUTICAL
HOLDING COMPANY LLC, and AMNEAL
PHARMACEUTICALS PVT. LTD,

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively “Par”), for their complaint against Amneal Pharmaceuticals Company GmbH, Amneal Pharmaceuticals of New York, LLC, Amneal Biosciences LLC, Amneal Pharmaceutical Holding Company LLC, and Amneal Pharmaceuticals Pvt. Ltd. (collectively “Amneal”), hereby allege as follows:

PARTIES

1. Plaintiff Par Pharmaceutical, Inc. (“Par Pharmaceutical”) is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical develops, manufactures, and markets pharmaceutical products in the United States.

2. Plaintiff Par Sterile Products, LLC (“Par Sterile Products”) is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Sterile Products develops, manufactures, and markets injectable pharmaceutical products, and provides manufacturing services to the biopharmaceutical and pharmaceutical industry.

3. Plaintiff Endo Par Innovation Company (“EPIC”) is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

4. Upon information and belief, Amneal Pharmaceuticals Company GmbH (“Amneal GmbH”) is a limited liability company organized and existing under the laws of Switzerland, having its principal place of business at Turmstrasse 30 6312, Steinhausen, Switzerland. Upon information and belief, Amneal GmbH is a pharmaceutical company engaged in the research, development, production, distribution, and sale of generic pharmaceuticals throughout the United States, including sales within this judicial district.

5. Upon information and belief, defendant Amneal Pharmaceuticals of New York, LLC (“Amneal New York”) is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 50 Horseblock Road, Brookhaven, New York 11719. Upon information and belief, Amneal New York is the U.S. agent for Amneal GmbH. Upon information and belief, Amneal New York is a pharmaceutical company engaged, among other things, alone and/or in concert with other Amneal Defendants, in the development, production, distribution, and sale of generic pharmaceuticals throughout the United States, including sales within this judicial district.

6. Upon information and belief, defendant Amneal Biosciences LLC (“Amneal Biosciences”) is a limited liability company organized and existing under the laws of Delaware, having its principle place of business at 400 Crossing Boulevard, Floor 3, Bridgewater, New Jersey 08807. Upon information and belief, Amneal Biosciences is a pharmaceutical company engaged, among other things, in at least the distribution of pharmaceutical products throughout the United States, including in this judicial district.

7. Upon information and belief, defendant Amneal Pharmaceuticals Holding Company LLC. (“Amneal Holding”) is a limited liability corporation organized and existing under the laws of Delaware, having its principal place of business at 440 US Highway 22 East, Suite 104, Bridgewater, New Jersey 08807. Upon information and belief, Amneal Holding is a pharmaceutical company engaged, among other things, in concert with other Amneal Defendants, in the development, production, distribution, and sale of generic pharmaceuticals throughout the United States, including sales within this judicial district.

8. Upon information and belief, defendant Amneal Pharmaceuticals Pvt. Ltd. (“Amneal India”) is a corporation organized and existing under the laws of India, having its principal place of business at Plot No. 15, PHARMEZ Special Economic Zone, Sarkhej-Bavia N.H., No. 8A, Vil.: Matoda, Tal.: Sanand, Ahmedabad, Gujarat 382213, India. Upon information and belief, Amneal India is a pharmaceutical company engaged, among other things, alone and/or in concert with other Amneal Defendants, in the manufacturing, packaging, testing, distribution and sale of pharmaceutical products for sold in and imported into the United States.

NATURE OF ACTION

9. This is an action for infringement of United States Patent Nos. 9,744,209 (“the ’209 Patent”) and 9,750,785 (“the ’785 Patent”) (collectively, “the Patents-in-Suit”). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) (patent infringement).

11. This Court has personal jurisdiction over Amneal New York because, *inter alia*, Amneal New York resides in this District and has purposely availed itself of the benefits and protections of the laws of Delaware. In addition, on information and belief, Amneal New York has had continuous and systematic contacts with this judicial district, including conducting business in Delaware and marketing, selling, and distributing pharmaceutical products throughout the United States and in this judicial district.

12. This Court has personal jurisdiction over Amneal GmbH because, *inter alia*, Amneal New York serves as the US agent for Amneal GmbH, and Amneal New York resides in this District. Amneal GmbH has therefore purposely availed itself of the benefits and protections of the laws of Delaware. In addition, on information and belief, Amneal GmbH has had continuous and systematic contacts with this judicial district, including conducting business in Delaware, including by acting in partnership and agency with the other Amneal Defendants, and marketing, selling, and distributing pharmaceutical products throughout the United States and in this judicial district. Upon information and belief, if the FDA approves the accused products for commercial sale in the U.S., Amneal GmbH will engage, on its own and/or in concert with the other Amneal Defendants, in the commercial manufacture, use, offer for sale, sale, and/or

importation into the United States of those products, including the commission of acts of infringement in or directed to this District.

13. This Court has personal jurisdiction over Amneal Biosciences because, *inter alia*, Amneal Biosciences resides in this District and has purposely availed itself of the benefits and protections of the laws of Delaware. In addition, on information and belief, Amneal Biosciences has had continuous and systematic contacts with this judicial district, including conducting business in Delaware and marketing, selling, and distributing pharmaceutical products throughout the United States and in this judicial district.

14. This Court has personal jurisdiction over Amneal Holding because, *inter alia*, Amneal Holding resides in this District and has purposely availed itself of the benefits and protections of the laws of Delaware. In addition, on information and belief, Amneal Holding has had continuous and systematic contacts with this judicial district, including conducting business in Delaware and marketing, selling, and distributing pharmaceutical products throughout the United States and in this judicial district.

15. This Court has personal jurisdiction over Amneal India because, *inter alia*, Amneal New York resides in this District and has purposely availed itself of the benefits and protections of the laws of Delaware. In addition, on information and belief, Amneal India has had continuous and systematic contacts with this judicial district, including conducting business in Delaware, including by acting in partnership and agency with the other Amneal Defendants, and marketing, selling, and distributing pharmaceutical products throughout the United States and in this judicial district. Upon information and belief, if the FDA approves the accused products for commercial sale in the U.S., Amneal India will engage, on its own and/or in concert with the other Amneal Defendants, in the commercial manufacture, use, offer for sale, sale,

and/or importation into the United States of those products, including the commission of acts of infringement in or directed to this District. Alternatively, this Court may exercise personal jurisdiction over Amneal India pursuant to Federal Rule of Civil Procedure 4(k)(2).

16. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b) because, *inter alia*, Amneal New York, Amneal Biosciences, and Amneal Holding are incorporated in Delaware, and thus reside in this district. Further, Amneal New York serves as the U.S. agent for Amneal GmbH. Further, all Defendants have collectively engaged in a course of conduct to seek approval for, manufacture, distribute, market, and sell the infringing products throughout the United States, including in this judicial district.

THE DRUG APPROVAL PROCESS

17. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the U.S. Food and Drug Administration (“FDA”), typically through the filing of a New Drug Application (“NDA”). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit to FDA information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, and FDA then lists the patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the “Orange Book.” *See* 21 U.S.C. § 355(b)(1) and (c)(2).

18. Alternatively, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an Abbreviated New Drug Application (“ANDA”). *See* 21 U.S.C. §355(j). The generic drug approval process is considered “abbreviated” because the generic manufacturer may piggyback on the innovator company’s data and FDA’s prior finding of safety and efficacy by demonstrating, among other

things, that the generic product is bioequivalent to the previously approved drug (the “listed drug” or “branded drug”).

19. In conjunction with this “abbreviated” application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify, for instance, that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This is known as a “Paragraph IV Certification.”

20. The filer of an ANDA with a Paragraph IV Certification must also provide notice to both the owners of the listed patents and the holder of the NDA for the referenced listed drug. This “Paragraph IV Notice” must include a detailed statement of the factual and legal bases for the applicant’s belief that the challenged patent is invalid or not infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

21. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to the innovator companies because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to an infringing product without first providing an opportunity for the infringement case to be resolved. Put another way, the innovator company is assured of a 30-month period during which it may try to enforce its

intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

FACTUAL BACKGROUND

The Patents-In-Suit

22. On August 29, 2017, the PTO duly and legally issued the '209 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '209 Patent is attached as Exhibit A. Par Pharmaceutical owns the '209 Patent.

23. On September 5, 2017, the PTO duly and legally issued the '785 Patent, entitled "Vasopressin Formulations For Use In Treatment Of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '785 Patent is attached as Exhibit B. Par Pharmaceutical owns the '785 Patent.

24. EPIC is the exclusive licensee of the Patents-In-Suit.

VASOSTRICT®

25. Vasopressin, the active ingredient in VASOSTRICT® (described below), is a polypeptide hormone that causes contraction of vascular and other smooth muscle cells. VASOSTRICT® is a lifesaving drug often used when the blood pressure of a critical care patient drops precipitously.

26. On September 25, 2012, JHP Pharmaceuticals ("JHP") submitted NDA No. 204485, under §505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) seeking FDA approval for a vasopressin injection product to increase blood pressure in adults with vasodilatory shock. On April 17, 2014, the FDA approved NDA 204485 as the first FDA-approved vasopressin injection product for use in a clinical setting in the United States.

27. On February 20, 2014, Par Pharmaceutical Companies, Inc. acquired JHP Pharmaceuticals, LLC. On February 26, 2014, JHP Pharmaceuticals, LLC changed its name to Par Sterile Products, LLC.

28. Par Sterile Products submitted supplemental NDAs including supplemental NDA Nos. 204485/S-003 and 204485/S-004 for the current formulations of VASOSTRICT®—20 units/mL in 1 mL vials and 200 units/10 mL in 10 mL multi-dose vials. On March 18, 2016, the FDA approved NDA No. 204485/S-003 for the 20 units/mL in 1 mL vial formulation of VASOSTRICT®. On December 17, 2016, the FDA approved NDA No. 204485/S-004 for the 200 units/10 mL in 10mL vial formulation of VASOSTRICT®.

29. Par Sterile Products is the holder of NDA 204485, including all supplements thereto, for VASOSTRICT®.

30. Par timely submitted information regarding the Patents-in-Suit for listing in the “Orange Book” with respect to VASOSTRICT®, pursuant to 21 U.S.C. § 355(b)(1) and (c)(2). The FDA thereafter listed the Patents-in-Suit in the Orange Book, pursuant to 21 C.F.R. § 314.53(e).

31. VASOSTRICT® is FDA-approved as indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Par markets and sells its VASOSTRICT® products to hospitals, both directly and via group purchasing organizations and wholesalers. VASOSTRICT® has enjoyed tremendous commercial success, with 2017 annual sales of \$400 million.

Amneal’s Infringing Generic Vasopressin Injection Product

32. Upon information and belief, Amneal has submitted ANDA No. 212944 (the “Amneal Single-Dose ANDA”) to the FDA pursuant to 35 U.S.C. § 355(j), seeking approval to

engage in the commercial manufacture, use, and sale of a proposed generic Vasopressin Injection USP, 20 units/1 mL (20 units/mL) product, referencing Par's VASOSTRICT® products as the reference listed drug (the "Proposed Single-Dose ANDA Product").

33. On or about March 5, 2019, Amneal sent Par Sterile Products and Par Pharmaceutical a notice stating that Amneal had submitted the Amneal Single-Dose ANDA seeking approval to manufacture, use, or sell the Proposed Single-Dose ANDA Product prior to expiration of the Patents-in-Suit (the "Single-Dose Paragraph IV Notice").

34. The Single-Dose Paragraph IV Notice advised that Amneal's Single-Dose ANDA includes Paragraph IV Certifications stating that it is Amneal's opinion that the Patents-in-Suit are invalid and not infringed by the Proposed Single-Dose ANDA Product.

35. Upon information and belief, Amneal has also submitted ANDA No. 212945 (the "Amneal Multi-Dose ANDA") to the FDA pursuant to 35 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic Vasopressin Injection USP, 200 units/10 mL (20 units/mL), referencing Par's VASOSTRICT® products as the reference listed drug (the "Proposed Multi-Dose ANDA Product").

36. On or about March 5, 2019, Amneal sent Par Sterile Products and Par Pharmaceutical a notice stating that Amneal had submitted the Amneal Multi-Dose ANDA seeking approval to manufacture, use, or sell the Proposed Multi-Dose ANDA Product prior to expiration of the Patents-in-Suit (the "Multi-Dose Paragraph IV Notice").

37. The Multi-Dose Paragraph IV Notice advised that Amneal's Multi-Dose ANDA includes Paragraph IV Certifications stating that it is Amneal's opinion that the Patents-in-Suit are invalid and not infringed by the Proposed Multi-Dose ANDA Product.

38. Upon information and belief, if Amneal were to obtain FDA approval to market and sell its Single-Dose and/or Multi-Dose ANDA Products, it would market and sell them throughout the United States, including in this District.

39. Defendants are inter-related corporate affiliates that share common ownership. Upon information and belief, they have and will act together in concert, as agents and partners of one another, to engage individually and/or collectively in the infringing acts described herein.¹

COUNT I:
INFRINGEMENT OF THE ‘785 PATENT (AMNEAL ANDA 212944)

40. Par incorporates each of the preceding paragraphs as if fully set forth herein.

41. Amneal’s submission of the Amneal Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose ANDA Product prior to the expiration of the ‘785 Patent, constitutes infringement of the ‘785 Patent under 35 U.S.C. § 271(e)(2)(A).

42. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose ANDA Product before expiration of the ‘785 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the ‘785 Patent under 35 U.S.C. §§ 271(a)-(c).

¹ Confidentiality obligations imposed by Amneal pursuant to the terms of its Offers of Confidential Access to its ANDAs preclude Par from providing greater specificity with respect to each individual corporate affiliate’s actual and anticipated role in the manufacture, marketing, distribution, sale and/or importation of Amneal’s Single-Dose and Multi-Dose ANDA Products, and Par reserves the right to take further discovery concerning those relationships.

43. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose ANDA Product would lead to such infringement of at least claim 1 of the '785 Patent, which recites as follows:

Claim 1: A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%; wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, and wherein the unit dosage form has a pH of 3.7-3.9.

44. The Proposed Single-Dose ANDA Product satisfies each of the elements of the pharmaceutical composition recited in claim 1, such that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose ANDA Product by Amneal would constitute infringement of claim 1 of the '785 Patent.

45. Any launch by Amneal of its Proposed Single-Dose ANDA Product before expiration of the '785 Patent would cause Par to suffer immediate and irreparable harm.

46. Upon information and belief, Amneal was aware of the existence of the '785 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose ANDA Product infringes the '785 Patent.

47. Amneal's infringement of the '785 Patent is willful.

COUNT II:
INFRINGEMENT OF THE '209 PATENT (AMNEAL ANDA 212944)

48. Par incorporates each of the preceding paragraphs as if fully set forth herein.

49. Amneal's submission of the Amneal Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose ANDA Product prior to the expiration of the '209 Patent, constitutes infringement of the '209 Patent under 35 U.S.C.

§ 271(e)(2)(A).

50. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose ANDA Product before expiration of the '209 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '209 Patent under 35 U.S.C. §§ 271(a)-(c).

51. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose ANDA Product would lead to such infringement of at least claim 1 of the '209 Patent, which recites as follows:

Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof; wherein:
the unit dosage form has a pH of 3.7-3.9;
the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;
the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
the human is hypotensive.

52. If the Proposed Single-Dose ANDA Product is administered as intended, doctors, nurses and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Amneal would actively and intentionally induce such infringement.

53. Any launch by Amneal of its Proposed Single-Dose ANDA Product before expiration of the '209 Patent would cause Par to suffer immediate and irreparable harm.

54. Upon information and belief, Amneal was aware of the existence of the '209 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose ANDA Product will lead to infringement of the '209 Patent.

55. Amneal's infringement of the '209 Patent is willful.

**COUNT III:
INFRINGEMENT OF THE '785 PATENT (AMNEAL ANDA 212945)**

56. Par incorporates each of the preceding paragraphs as if fully set forth herein.

57. Amneal's submission of the Amneal Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose ANDA Product prior to the expiration of the '785 Patent, constitutes infringement of the '785 Patent under 35 U.S.C. § 271(e)(2)(A).

58. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose ANDA Product before expiration of the '785 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '785 Patent under 35 U.S.C. §§ 271(a)-(c).

59. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose ANDA Product would lead to such infringement of at least claim 1 of the '785 Patent, which recites as follows:

Claim 1: A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%; wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, and wherein the unit dosage form has a pH of 3.7-3.9.

60. The Proposed Multi-Dose ANDA Product satisfies each of the elements of the pharmaceutical composition recited in claim 1, such that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose ANDA Product by Amneal would constitute infringement of claim 1 of the '785 Patent.

61. Any launch by Amneal of its Proposed Multi-Dose ANDA Product before expiration of the '785 Patent would cause Par to suffer immediate and irreparable harm.

62. Upon information and belief, Amneal was aware of the existence of the '785 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose ANDA Product infringes the '785 Patent.

63. Amneal's infringement of the '785 Patent is willful.

**COUNT IV:
INFRINGEMENT OF THE '209 PATENT (AMNEAL ANDA 212945)**

64. Par incorporates each of the preceding paragraphs as if fully set forth herein.

65. Amneal's submission of the Amneal Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose ANDA Product prior to the expiration of the '209 Patent, constitutes infringement of the '209 Patent under 35 U.S.C. § 271(e)(2)(A).

66. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose ANDA Product before expiration of the '209 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '209 Patent under 35 U.S.C. §§ 271(a)-(c).

67. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose ANDA Product would lead to such infringement of at least claim 1 of the '209 Patent, which recites as follows:

Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof; wherein:
the unit dosage form has a pH of 3.7-3.9;
the unit dosage form further comprises impurities that are present in an amount of

0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
the human is hypotensive.

68. If the Proposed Multi-Dose ANDA Product is administered as intended, doctors, nurses and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Amneal would actively and intentionally induce such infringement.

69. Any launch by Amneal of its Proposed Multi-Dose ANDA Product before expiration of the '209 Patent would cause Par to suffer immediate and irreparable harm.

70. Upon information and belief, Amneal was aware of the existence of the '209 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose ANDA Product will lead to infringement of the '209 Patent.

71. Amneal's infringement of the '209 Patent is willful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following relief:

A. A judgment that Amneal has infringed the '785 Patent, and a declaration that Amneal's commercial manufacture, distribution, use, and sale of its Proposed Single-Dose ANDA Product would infringe the '785 Patent;

B. A judgment that Amneal has infringed the '785 Patent, and a declaration that Amneal's commercial manufacture, distribution, use, and sale of its Proposed Multi-Dose ANDA Product would infringe the '785 Patent;

C. A judgment that Amneal has infringed the ‘209 Patent, and a declaration that Amneal’s commercial manufacture, distribution, use, and sale of its Proposed Single-Dose ANDA Product would induce infringement of the ‘209 Patent;

D. A judgment that Amneal has infringed the ‘209 Patent, and a declaration that Amneal’s commercial manufacture, distribution, use, and sale of its Proposed Multi-Dose ANDA Product would induce infringement of the ‘209 Patent;

E. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Amneal’s Single-Dose ANDA No. 212944 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the last expiration date of the Patents-in-Suit, including any extensions;

F. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Amneal’s Multi-Dose ANDA No. 212945 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the last expiration date of the Patents-in-Suit, including any extensions;

G. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283, restraining and enjoining Amneal, its officers, agents, servants and employees, and those person in active concert or participation with any of them, from infringement of the Patents-in-Suit for the full terms thereof, including any extensions;

H. An order that damages or other monetary relief be awarded to Plaintiffs if Amneal engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of Amneal’s Proposed Single-Dose ANDA Products, or induces such conduct by others, prior to the expiration of the Patents-in-Suit, and any additional period of exclusivity to which Plaintiffs are

or become entitled, and that any such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment and post judgment interest;

I. An order that damages or other monetary relief be awarded to Plaintiffs if Amneal engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of Amneal's Proposed Multi-Dose ANDA Products, or induces such conduct by others, prior to the expiration of the Patents-in-Suit, and any additional period of exclusivity to which Plaintiffs are or become entitled, and that any such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment and post judgment interest;

J. Reasonable attorneys' fees, filing fees, and reasonable costs of suit incurred by Plaintiffs in this action; and

K. Such other and further relief as the Court may deem just and proper.

Dated: April 18, 2019

Respectfully submitted,

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